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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,197

09/21/2005

Young-Taek Sul

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EXAMINER

LEWIS, RALPH A

ART UNIT

PAPER NUMBER

3732

MAIL DATE

DELIVERY MODE

05/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,197	Applicant(s) SUL, YOUNG-TAEK	
	Examiner Ralph A. Lewis	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 13 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 13 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Acknowledgement of Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 9/22/2008; 10/23/2008 and 12/19/2008 have been entered.

Suspension of Action under 37 CFR 1.103(c)

The 3 month suspension of action requested in the petition of December 19, 2008 has expired.

Rejections based on Prior Art

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 13 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuilleron (FR 2610512 A) in view of Hansson et al. (US 5,588,838).

Cuilleron discloses an implant having a cylindrical core (Figure 5) with helical threads (2b) for screwing the implant into the intramedullary channel of a prepared

Art Unit: 3732

femur. Formed on the helical threads 2b is a continuous pattern of microthreadings (2c) that increase the exposed surface area of each helical thread 2b (see Figure 7).

Cuilleron also shows that implant threads can include inclined flanks have a continuum of micro-patterns thereon as shown clearly in Figure 4, said micro-patterns as shown having a polygonal cross-section. Examiner notes that the micro threads (1c) shown in Figure 4 comprise a series of recesses and protrusions incised thereon which form the aforementioned micro-patterns (i.e. triangular shaped patterns 1f, also representative of ridges). Furthermore, Examiner notes that Figure 4 also shows that each screw thread comprises crests (i.e. the free distal end of each thread) and roots (i.e. proximal base portion of each thread). The flanks (i.e. inclined sides of each thread) connect the crests with the roots. Lastly, because the polygonal cross-section of the micro-patterns can be triangular, Figure 4 demonstrates how their polygonal outline can appear open at one side (i.e. between crests of adjacent triangles) when viewed on a cross-sectional plane. Cuilleron further discloses that the micro-patterns located on the threadings can have a profile other than a triangular profile (i.e. see attached EPO automated translation, page 3, lines 1-3). Cuilleron, however, does not explicitly disclose that said micro-patterns have “continuous and repeated arcuate cross-sectional outlines” as required by the claims.

Hansson et al teach an implant that has continuous micro threads 9 (Figure 1) or alternatively microthreads formed by a continuous microbeads (Figure 3) (note column 3, lines 11-21). The microbeads have an arcuate design, wherein the spaces between each bead are identical grooves (i.e. microbeads; column 2, lines 34-37). In view of the

Art Unit: 3732

Hansson et al alternative teaching, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to use arcuate shaped micro-patterns in the threads of Cuilleron in order to avoid, or at least minimize, stress-concentrations in the bone tissue around said microthreads as taught by Hansson. Furthermore, Examiner notes that such an arcuate shape helps to avoid, or at least minimize, additional cutting into the bone of the patient during insertion, such that the patterns can be relied on instead for providing a region for bone-implant integration to occur.

Additionally, Cuilleron fails to disclose a specific distance between each micro-pattern, Hansson, however, teaches that the distance between adjacent threads may be approximately 0.2 mm (200 μ m) (column 2, line 28) which helps to provide for rapid bone growth into the microthreads (column 2, lines 53-59). Merely providing for similar such spacing (e.g. 150 μ m) for the undisclosed spacing of the Cuilleron microthreads in order to promote rapid bone growth into the microthreading would have been obvious to one of ordinary skill in the art. Moreover, it is noted that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable values involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

In the response of October 23, 2008 a declaration under 37 CFR1.132 by the inventor concluded that the "150 μ m micro-pattern provide optimal site for bone ingrowth" (paragraph 11) and provides evidence in the form of test results that show the ingrowth of bone into micro-patterns of 150 μ m. The examiner notes that the

Art Unit: 3732

declaration fails to provide results for any other spacings and as such fails to provide any basis for arguments that the results are unexpected or have any meaningful distinction over the similarly sized spacing of Hansson which is disclosed as promoting bone growth. Moreover, the mere testing of similarly sized spacings in order to find the most optimal spacing is not of no patentable merit, but rather the result of routine testing obvious to the ordinarily skilled artisan.

Applicant further argues in the response of 12/19/2008 the declaration when taken in context with the originally filed specification the claimed spacing is indeed optimal because it also factors in the desire to maintain the largest possible surface contact area between the implant and the bone. The examiner is not persuaded. One desiring to practice the Cuilleron invention would have to determine the spacing of the microthreads 2c on their own accord since Cuilleron is silent on the issue. Hansson et al teaches that for similar microthreads in a bone implant that thread spacing of around 200 μm is desirable because it provides for rapid bone growth. Merely, selecting similar spacing for the Cuilleron microthreading would simply be obvious to the ordinarily skilled artisan as a matter of routine practice.

Action Made Final

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3732

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

This application has been transferred since Examiner Werner is no longer with the Office. Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(571) 272-4712**. Fax (571) 273-8300. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Cris Rodriguez, can be reached at (571) 272-4964.

R.Lewis
May 11, 2009

/Ralph A. Lewis/
Primary Examiner, Art Unit 3732